The Pharma Code and the Pharma Cooperation Code in 2017: Annual Report of the Code Secretariat

Introduction

For many years, the Swiss pharmaceutical industry has applied internationally coordinated (see IFPMA[1], EFPIA[2]) self-regulation that goes beyond the law with the Pharma Code (PC[3]) and the Pharma Cooperation Code (PCC[3]). Pharmaceutical companies can voluntarily agree to abide with these codes (see lists of signatories[4]). While the PC primarily aims to encourage ethically correct conduct and avoid unfair competition, the PCC mainly seeks to promote transparency of pecuniary benefits granted under the cooperation between the pharmaceutical companies and their partners in the healthcare system.

The support organisation for pharmaceutical self-regulation in Switzerland is scienceindustries, while its Code Secretariat is responsible for the implementation of the codes. When dealing with disputes, the Secretariat primarily acts as an intermediary and applies the principle of the amicable settlement of conflicts. In 2017 too, its neutral assessment was almost always accepted by the parties involved in the individual disputes and the situation was soon returned to compliance with the Code and the law. The impressive number of cases once again confirms the universal respect for this procedure, in particular the ease of access and the rapid and transparent decisions taken.

Statistics regarding implementation of Pharma Code in 2017

At 121 (2016: 119), the number of cases dealt with in connection with the PC increased slightly. The number of complaints filed against competitors declined substantially from 54 in 2016 to 39. There were no other complaints (2016: one complaint filed by a legal representative). No cases were classified as potentially hazardous to health (2016: one), and to the best of the Secretariat's knowledge, no cases were escalated to Swissmedic (2016: three). Sixty-four pharma companies submitted 4,657 sample copies of their promotional material and information; 3,625 sample copies (77.8%) were sent to the Secretariat electronically.

The average duration of proceedings increased from 6.1 days in 2016 to 8.7 days in the reporting year. This increase was caused by several very complex cases, some of which referred to previous cases and therefore required time-intensive research. It can be confirmed that the companies concerned as a rule complied with the process and responded quickly and constructively.

In 2017, 90 proceedings were concluded (74% of all the cases dealt with as against 69 or 68% in the previous year) after the contested advertising had either been corrected or removed. The Secretariat rejected 8 (7%) of the complaints (previous year: 17 or 27%) because there had been no breach of the Code. In three cases (2%; previous year: 7 or 8%) the concluding letter to the company responsible imposed a condition requiring an amendment to comply with the Code; in no cases (previous year: two) an immediate correction of the advertising was required. In two cases (previous year: one), the immediate and complete withdrawal of the disputed advertising was required. All the conditions imposed were accepted by the responsible companies and implemented in a timely manner. In 24 cases (20%; previous year 6 or 10%), the denounced company offered new interpretations, necessitating a review by the Secretariat, and in one case the Code Secretariat carried out a mediation procedure. As in the previous year, the Code Secretariat was aware of six bilateral negotiations in 2017. As there is no obligation to notify bilateral negotiations, the actual number remains unknown.

In the reporting year, the Code Secretariat answered some 200 enquiries, mostly from member companies, but a considerable number were also from professional associations, congress organisers, law offices and other interested groups.

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[1] IFPMA
[2] EFPIA
[3] The provisions of the two codes are referred to in the Annual Report by “PC” and “PCC” with the relevant section number.
[4] Signatories of the Pharma Code / Signatories of the Pharma Cooperation Code

Established breaches of the Code

The total of 121 complaints regarding suspected PC breaches referred to 38 different PC requirements. Around two requirements were mentioned per complaint. The following is a list of the six PC requirements that were mentioned ten times or more. These six requirements played a role in around 60% of all cases brought before the Code Secretariat in 2017. This list is followed by a selection of relevant requirements that led to a complaint regarding a suspected breach less often:

- Principle of professional promotions (PC 21): at 12 (previous year: 5), the number of these cases increased considerably.
- Unproven advertising statements (PC 251): at 24 (previous year: 25), the number of cases was stable at a high level.
- Incorrectly cited references (PC 252): at 30 (previous year: 28), the number of cases was stable at a high level.
- Incomplete or impermissible references to literature (PC 26, 261 to 266): the number of cases increased further to 60 (previous year: 49).
- Notifications of unqualified superlatives and comparatives (PC 267, 268): the number of cases declined sharply to 10 (previous year: 37).
- Inducement to attend a specialist conference (PC 313): 18 cases compared to 0 in the previous year.

- Ban on gifts (PC 142): two complaints were received (previous year: one).
- Promotional statements differing from the drug information for health professionals approved by Swissmedic at the time when marketing authorisation was given (PC 233): the number of cases (6) declined sharply from the previous year (17).
- Promoting as-yet unauthorised medicinal products or indications (PC 231, 232, 241 and 242): the number of cases declined considerably (one case, previous year: 16).
- Use of the expression “safe” without an appropriate qualification (PC 253.1): three cases were reported (previous year: one).
- Promotional materials that did not contain all the minimum information about pharmaceuticals required by the PC (PC 254 and 255): the number of cases rose substantially to 37 (previous year: 13).
- Use of expressions minimising possible risks, for example claiming that the medicinal product concerned did not induce addiction or was harmless (PC 253.2): slight decline to three cases (previous year: 5).
- Designating mailings as an “important notice” (PC 28 – allowed solely to maintain pharmaceutical safety and in the event of interruption or suspension of delivery of a pharmaceutical): the Secretariat recorded two cases again (previous year: one).
- Complaints regarding serious breaches of the Code (PC 641): no cases were recorded (previous year: one).
- Referral of a matter to the appropriate State authority (PC 651): here too, no cases were recorded (previous year: one).

Support for events promoting postgraduate medical training and continuing medical education (PC 3)

In 2017, the Code Secretariat of its own accord as well as at the request of companies or organisations again reviewed a number of events promoting postgraduate medical training and continuing medical education to check whether they meet the self-regulation requirements. In doing so, the Secretariat applied established international standards (in particular IPCAA[5] and e4ethics[6]). Intervention was needed in 18 cases, whereby 9 congress organisers and/or professional associations were contacted directly. The discussions were constructive and as a rule agreement could be reached with the organisers to structure the events correctly in compliance with the guidelines and the ethical principles. In one case the Secretariat was unable to issue a recommendation to support the event in question. The Secretariat's increased efforts in this field also led to an increase in enquiries from affected organisations.

[5] Guidelines of the International Pharmaceutical Congress Advisory Association – IPCAA
[6] https://www.ethicalmedtech.eu/e4ethics/about-e4ethics

Implementation of Pharma Cooperation Code

Between 20 and 30 June 2017, the companies that signed the PCC for the second time disclosed the pecuniary benefits granted in 2016 to healthcare professionals (HCP, mainly doctors and pharmacists), healthcare organisations (HCO, mainly hospitals and professional organisations) and patient organisations (PO) on their websites. Pecuniary benefits as defined by the PCC are benefits granted either directly or indirectly for cooperation with the above-mentioned groups in connection with prescription medicinal products for human use and in connection with research and development (R&D).

To ensure as much transparency as possible, disclosure should be made on an individual basis, i.e. by naming the person who received a benefit, which requires the recipients to agree to the disclosure. Consent rates were higher on average in 2017. Based on the number of recipients, some 73% of HCP and around 85% of HCO agreed to individual disclosure. These rates are considerably higher than in the other German-speaking countries, which is encouraging. However, it seems that, in some cases, consent rates have resulted in considerable discrepancies in the individual companies, which are sometimes rather difficult to understand. The Code Secretariat encouraged the PCC signatory companies to keep up their efforts to maintain their high rates or to increase these rates to at least 80%. scienceindustries remained in close contact with the groups concerned, informed the FMH[7] at its meeting of delegates about the result of the 2016 disclosure, and successfully promoted continuous support of the transparency initiative. In June 2017, scienceindustries also added what is termed a gateway[8] to its website that refers directly to the disclosure reports of the individual signatory companies. As this makes the search for information easier for the interested parties, it was welcomed accordingly.

The Code Secretariat immediately checked the data upon publication to ensure that they were complete and published on time in accordance with the requirements of the PCC. For a few companies, there was a short delay in the publication of their data, but completely published data quality could be reached slightly quicker than in the previous year, albeit not exactly on 1 July 2017.

The Code Secretariat has compiled the figures of the 59 companies that published data and by the beginning of August 2017, were able to put together the following statistics about Switzerland: At CHF 153.3 million, disclosures of transfers of value (ToV) increased by CHF 14.7 million from CHF 138.6 million in 2016, which is an increase of 11% on the previous year. CHF 14 million (9% of the total amount) was disclosed for HCP compared to CHF 15.5 million (11% of the total amount) in 2016, which is down 9% on the previous year. A total of CHF 90 million ToV (59% of the total amount) was disclosed for HCO compared to CHF 75.5 million (55% of the total amount) in 2016, which is almost 20% more than in the previous year. ToV of CHF 49 million (32% of the total amount) were disclosed for R&D services, compared to CHF 47.5 million (34% of the total amount) in 2016, which represents a year-on-year change of almost 3%. Relatively high amounts were thus paid to HCO in Switzerland again compared to the rest of Europe, while the payments to HCP were lower than the European average. This confirms the impression that a substantial proportion of these HCO payments were made to international professional associations that have offices in Switzerland, which may at least be partially due to the need for these organisations to be located near the World Health Organisation (WHO) headquarters in Geneva.

With regard to the practical implementation of the transparency initiative, ToV to intermediary organisations (e.g. congress organisers) are proving to be a particular challenge, and the requirements of the European association could only be partly implemented in this segment. The signatory companies, however, countered this rather mixed practice of disclosure by providing more details in their "Explanatory notes". The Code Secretariat and the Code Commission met these difficulties by providing additional guidance on the term HCO. This topic will continue to be followed closely, both in the international and national context.

Code Secretariat

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[7] FMH
[8] Linked list of PCC signatories